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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : JIN, et al.

U.S. Serial No.: 09/886,555 (claiming benefit of U.S. Serial No. 60/214,037, filed June 23, 2000)

Filed : June 21, 2001

For : STABLE POLYMER AQUEOUS/AQUEOUS EMULSION SYSTEM AND USES THEREOF

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August 3, 2001

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with his duty of disclosure under 37 C.F.R. §1.56, applicant would like to direct the Examiner's attention to the following references which are listed on Form PTO-1449 (which is attached hereto as **Exhibit A**) and each individual reference is further attached as **Exhibits 1** through **17**, respectively:

1. PCT Patent Publication No. WO 98/00170, January 8, 1998, W. Hennink and W. Van Dijk-Wolthuis, "Hydrolysable Hydrogels for Controlled Release" [**Exhibit 1**]
2. PCT Patent Publication No. WO 98/22893, May 28, 1998, W. Hennink and O. Franssen, "Process for the Preparation of a Controlled Release System" [**Exhibit 2**]
3. "Biodegradable dextran microspheres for controlled release of pharmaceutical proteins," OctoPlus, 21-24, March 2000 [**Exhibit 3**]
4. R. Langer and J. Folkman, "Polymers for the sustained release of proteins and other macromolecules;" Nature, 263, 797-800 (1976) [**Exhibit 4**]
5. S. Cohen and H. Bernstein, Microparticulate Systems for the Delivery of Proteins and Vaccines; Marcel Dekker, New York, 1996 [**Exhibit 5**]

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6. R. Bodmeier, H. Chen, P. Tyle and P. Jarosz, "Pseudoephedrine HCl microspheres formulated into an oral suspension dosage form;" *J. Controlled Rel.*, **15**, 65-77 (1991) [Exhibit 6]
7. M.J. Alonso, P.K. Gupta, C. Min, G.R. Siber and R. Langer, "Biodegradable microspheres as controlled-release tetanus toxoid delivery systems;" *Vaccine*, **12**, 299 (1994) [Exhibit 7]
8. R.J. Henry and C.P. Szustkiewicz, "The Preparation of Protein-Free Filtrates," in **Clinical Chemistry, Principals and Technics**; R.J. Henry, edit; Press: Harper & Row, 1984 [Exhibit 8]
9. T. Fabilloud, C. Gelfi, M.L. Bossi, and P.G. Righetti, "Protein Precipitation induced by alkaline Immobilines for isoelectric focusing in immobilized pH gradients: Causes and remedies," *Electrophoresis*, **8**, 305-312 (1987) [Exhibit 9]
10. E.Z. Zaslavsky, **Aqueous Two-Phase Partitioning**; Marcel Dekker, New York, 1984 [Exhibit 10]
11. E.A. Albertsson, **Partition of Cell Particles and Macromolecules**, 3rd ed. Wiley, New York, 1996 [Exhibit 11]
12. AmBisome® packaging insert, marketed by Fujisawa, Developed by NeXstar [Exhibit 12]
13. N. T. Parkin, P. Chiu, and R. Coelinph, "Genetically-engineered live attenuated influenza A virus vaccine candidates;" *J.Virol.*, **74**, 2772-2778 (1997) [Exhibit 13]
14. E. Sakmann, "Supported Membranes: Scientific and Practical Applications;" *Science*, **271**, 43-48, (1996) [Exhibit 14]
15. R.J. Lee, L. Huang, "Gene Transfer by Liposome-Entrapped Polycation-Condensed DNA: LPDI and LPDII," in **Artificial Self-Assembling Systems for Gene Transfer**, P.L. Felgner et al. ed., American Chemical Society, Washington DC, 1996 [Exhibit 15]
16. I. Zarif, I. Segarra, T. Jin, D. Hyra, R.J. Mannino; "Amphotericin B Cochleates as a Novel Oral Delivery System for the Treatment of Fungal Infections;" 26th International Symposium on Controlled Release of Bioactive Materials; Boston, USA, 1999 [Exhibit 16]

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17. R.J.H. Stenekes, O. Franssen, E.M.G. van Bommel, D.J.A. Crommelin, and W.E. Hennick "The use of aqueous PEG/dextran phase separation for the preparation of dextran microspheres;" Int'l Jour. of Pharmaceutics, Elsevier, 183, 29-32 (1999) [Exhibit 17]

No fee is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

I hereby certify that this paper is being deposited this date with the U.S. Postal Service as first class mail addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

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